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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|---------------------------|---------------------|------------------|
| 10/626,499 | 07/24/2003 | Manne Satyanarayana Reddy | U 014732-3 | 1978 |

7590

11/09/2005

Ladas & Parry
26 West 61 Street
New York, NY 10023

EXAMINER

CHANG, CELIA C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1625

DATE MAILED: 11/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/626,499 | REDDY ET AL. | |
| | Examiner | Art Unit | |
| | Celia Chang | 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment and response filed by applicants dated Aug. 30, 2005 have been entered. A certified copy of the priority document has been submitted in the record.

2. The granting of the benefit for the priority date cannot be made in view of the priority document against the instant claims.

Please note that the priority document evidenced that the invention as defined by claim 1 of the priority document is an "improved process" for preparation of formula I which is substantially the process as the instant claim 19. No description or support was found for the instant claim 1 wherein no limitation was made in sequence, steps and parameters in the synthetic process.

3. The rejections of claims:

- a) 1-2,4-6, 8-12 under 35 USC 102(e) over US 6,649,765;
- b) 1-2, 4-6, 8-12 under 35 USC 103(a) over US 6,649,765 in view of US 4,895,841;
- c) 1-2, 4-6, 8-12 under 35 USC 103(a) over US 6,649,765 in view of US 4,895,841 and Sugimoto et al. Bioorg. Med. Chem let, further in view of WO 97/22584;
- d) 1-2, 4-6, 8-9, 11-12 under 35 USC 103(a) over US 5,606,064 in view of US 4,895,841;
- e) 1-2, 4-6, 8-9, 11-12 under 35 USC 103(a) over US 5,606,064 in view of US 4,895,841 and Sugimoto et al. Bioorg. Med Chem. Let;
- f) 1-33 under 35 USC 103(a) over US 5,606,064 in view of US 4,895,841 and Sugimoto et al. Bioorg. Med Chem. Let further in view of WO 97/22584

are maintained for reason of record.

Please note that the priority document evidenced that the disclosed invention of the priority document is not *identical* to claim 1 since the priority document is an improved process with specific sequence and more limited conditions then the instantly claimed process.

Art Unit: 1625

The gist of applicants argument is that the “[Sugimoto et al.] patent i.e. ‘841 disclosed the preparation of donepezil by reacting 1-benzyl-4-piperidinecarbaldehyde with 5,6-dimethoxy -1-indanone in presence of n-butyllithium” (see p. 13 response), thus, none of the rejection can be combined. Please note that this argument is erroneous, because there is **no limitation** in the claims to demarcate from this process or excluding such scope.

4. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

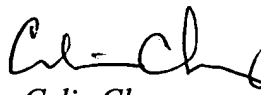
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Nov. 3, 2005


Celia Chang
Primary Examiner
Art Unit 1625